Opening Statement
Of
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Under Secretary for Health
U.S. Department of Veterans Affairs

May 12, 1999

PREVENTABLE ADVERSE DRUG EVENTS
NATIONAL PATIENT SAFETY PARTNERSHIP

We are here today to talk about a serious public health problem – a problem that has been recognized and talked about for many years, a problem that some experts believe is getting worse, and a problem for which there are readily available and cost effective solutions.

Ironically, this problem of preventable adverse drug events stems from one of the great healthcare success stories of the 20th century, the development of generally safe pharmaceutical products that effectively treat so many different illnesses and health conditions.

As representatives of our individual organizations and as members of the National Patient Safety Partnership we are here today to say it is time to act; it is time to begin to definitively address this problem. In doing this we call upon pharmaceutical manufacturers, healthcare provider organizations, physicians and other caregivers, as well as patients and their families, to each exercise their influence to reduce preventable adverse drug events. In making this call to action we also provide a prescription that if followed could cure three-fourths, if not more, of the problem.

How big of a problem is preventable adverse drug events?

Adverse drug events injure or disable many tens of thousands of Americans every year and add billions of dollars to health care costs. One of the problems is that while we know this is a serious problem, the exact extent of the problem is not known even though many studies of adverse drug events have been published in the medical literature over the past thirty years. These studies show that, on average, about 7% of hospitalized patients will have an adverse drug event. One recent study indicated that as many as 2 million patients may experience an adverse drug event each year. Recent studies have also shown that each one of these events, on average, adds several days of hospitalization to the hospital admission and several thousand dollars to the cost of the hospital stay. We know much less about the frequency or cost of these events in ambulatory or outpatient care, nursing homes, and other sites of care.

In addition, we know that the majority of these adverse drug events are preventable. Indeed, the good news is that these events are preventable with relatively simple interventions. If these simple and straightforward solutions, such as we prescribe here to day, were implemented many thousands of injuries, disabilities and deaths could be prevented and hundreds of millions to billions of dollars of healthcare costs could be saved.

AMERICAN HOSPITAL ASSOCIATION STATEMENT
NATIONAL PATIENT SAFETY PARTNERSHIP PRESS CONFERENCE
ATTRIBUTE TO: JACK LORD, M.D., CHIEF OPERATING OFFICER, AHA
MAY 12, 1999

One of the most important priorities for hospital leaders is to eradicate medical errors in their institutions, and specifically, to reduce errors that occur when medicine is mishandled or misused – thereby endangering patients. The National Patient Safety Partnership recommendations to reduce medication errors will help health care providers make significant improvements.

Most hospitals have systems in place – checks and balances to ensure that errors won't occur. But unfortunately, medication errors can and do occur because of a lack of clear written and oral communication. Transferring information from manufacturer to hospital supply manager to nurse to doctor to patient involves a lot of communication that must be 100 percent accurate.

To identify the cause of errors and increase patient safety, we must increase our own level of awareness of errors that occur within our facilities. Hospitals – and all health care providers – need systems that will catch possible mistakes before they happen. And we believe that one of the most important steps toward improvement is to do what patients tell us they want – to become full partners in decisions about their care and treatment. Improved communication between care givers and patients should contribute to a decline in medication errors.

The AHA is a key player on many national initiatives aimed at reducing preventable medical errors: the National Coordinating Council for Medication Error, Reporting and Prevention; the Institute for Healthcare Improvement; the Institute for Safe Medication Practices; the AMA's National Patient Safety Foundation; and U.S. Pharmacopeia – a not-for-profit foundation to help pharmacists and physicians learn about medication error and prevention.

It will take the involvement of everyone – consumers, physicians, hospitals and other providers of care to prevent medication errors and improve the quality of care.

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U.S. Department of Health and Human Services
Food and Drug Administration
Rockville, MD
May 12, 1999

Earlier this week FDA released a report on managing the risks from medical products. The report acknowledges that all medical products have inherent risks, and that saying a product is "safe" does not mean that it is without risk.

The report emphasizes the advantages of a systems approach to managing that risk. Every group involved in health care – regulators, physicians, patients, others – has its own role. When those roles are clearly defined and acted on, the benefits of medical products will be maximized and their risks minimized.

That's why one of the major recommendations of FDA's report calls for broad policy discussions with stakeholders. And that's why FDA is working closely with the National Patient Safety Partnership in its efforts.

The National Patient Safety Foundation at the AMA

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FOR IMMEDIATE RELEASE: MAY 12, 1999

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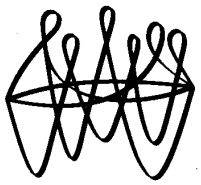

The National Patient Safety Foundation at the AMA (NPSF) recognizes that preventable adverse drug events are an important public health problem which present a challenge for all those involved with pharmaceuticals to communicate, cooperate, and collaborate to ensure their safe and appropriate use. The NPSF's commitment to meeting this challenge is reflected in its participation in the National Patient Safety Partnership Initiative to Reduce Preventable Adverse Drug Events and its facilitation of multidisciplinary, multifaceted systems approaches for the enhancement of patient safety and prevention of health care errors.

The best practices put forth today by the National Patient Safety Partnership include a "call to action" for ongoing collaboration and research to identify better practices. To this end, the NPSF is convening a pharmaceutical safety workshop on June 10-11, 1999 in Washington, DC. Representatives from all dimensions of the pharmaceutical safety chain – ranging from pharmaceutical research and design, regulation, prescribing, administering, dispensing, monitoring, and consumer end use – will convene to identify their roles and responsibilities for the safe and appropriate use of pharmaceuticals. Expected outcomes of this workshop include a consensus on the strengths and vulnerabilities of the system and the identification of existing tools and resources, and those that are still needed, to responsibly address pharmaceutical safety issues.

Founded in 1997, the National Patient Safety Foundation is a nonprofit research and education organization dedicated to the measurable improvement of patient safety in the delivery of health care. The Foundation has formed a unique partnership of health care clinicians, institutional providers, health product manufacturers, researchers, legal advisors, consumer advocates, regulators, and policy makers among its board of directors. Working collaboratively with its broad base of constituents, the NPSF is leading the patient safety movement by raising awareness, building a knowledge base, creating a forum for sharing that knowledge, and facilitating the implementation of practices that improve patient safety.

For further information about the activities of the NPSF, visit its web site at www.npsf.org.

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NATIONAL PATIENT SAFETY PARTNERSHIP

MEDIA STATEMENT
May 12, 1999

OVERHAUL OF HEALTH CARE PROCESSES NEEDED TO INCREASE PATIENT SAFETY

The Institute for Healthcare Improvement (IHI) is a non-profit organization committed to developing systems of care that ensure patients receive safe and timely care that results in the best possible health outcome.

IHI has been working on patient safety issues for many years and, as a member of the National Patient Safety Partnership, believes that reducing adverse drug events is a critical and achievable step in ensuring a safe health care system. The problem is well understood, the solutions well documented, and now is the time to commit to solving this grave problem together.

According to IHI CEO and President, Donald M. Berwick, MD, "Error rates in medicine are much too high for the safety and well-being of patients. Yet the traditional approach of blaming individuals for mistakes doesn't get at the heart of the real problem. What's needed -- and what actually reduces and prevents errors -- is a redesign of work systems," Dr. Berwick says. The system for processing a medication order is complex, involving multiple individuals, groups and departments. "In addition, time pressures, excessive work loads, variations in practices and the structure of the patient care environment contribute to inefficiencies and provide opportunities for error," says Dr. Berwick. "Health care organizations have a moral obligation to create systems of care that are 100% error-proofed."

Reducing Adverse Drug Events

According to research studies published in the January 1997 issue of *The Journal of the American Medical Associa*tion, each year between 770,000 and 2 million hospital patients experience what is known as an adverse drug event, such as respiratory arrest, kidney failure, rashes and itching, diarrhea and vomiting, costing $4.2 billion. Furthermore, studies show that nearly one-third of all adverse drug events are preventable.

In 1996 and 1998, IHI sponsored Collaboratives on Reducing Adverse Drug Events and Medical Errors involving nearly 100 organizations across the US. Under the guidance of improvement and medical experts, these organizations prevented and reduced medication errors -- some by as much as 50 percent -- by redesigning work processes and systems. These six-month-long Collaboratives teach safety principles and methods commonly used by other industries (e.g., aviation) and focus efforts on six key areas: improving prescribing practices; safe handling of lethal drugs; standardizing the medication process; improving access to information; improving chemotherapy safety; and facilitating error reporting.

In addition, technologies that vastly improve the safety of medication systems are available, including computerized physician order entry systems, bar-coded dispensing and administration systems, and automated dispensing systems on nursing units tied to pharmacy computers. Yet these technologies are slow to be adopted due to the expense and lack of understanding about errors and error prevention on the part of many health care executives.

About IHI

Founded in 1991 and based in Boston, IHI is an independent, non-profit organization working to improve health care quality worldwide by fostering collaboration, rather than competition, among health care organizations. Specific goals IHI works toward include: improved public health; better clinical outcomes; reduced costs that do not compromise quality; greater access to care; an easier to use health care system; and improved satisfaction among individuals and communities. Visit our web site at www.ihi.org for more information.

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HEALTH AFFAIRS

The Department of Defense strongly supports the efforts of the National Patient Safety Partnership to improve healthcare and patient safety through the prevention of adverse drug events.

The 16 best practices identified by the Partnership are important steps to be taken by healthcare organizations, purchasers, physicians, nurses, pharmacists and patients. These steps are based on strong research and clinical experience. They include improved medication packaging, labeling and dispensing, dosage adjustments for children and the elderly, and active involvement of patients. Providers, healthcare organizations and manufacturers should support these measures under the basic premise of medicine – first, do no harm.

In the Military Health System, many of the best practices endorsed by the National Patient Safety Partnership are widely used. Our military pharmacists work with patients to inform them of the need to review their medications, including over the counter medications, with their healthcare providers. Many of our pharmacies have patient education offices specifically designed to offer counseling regarding medications and to respond to patient questions about their prescriptions. Many also have programs where the pharmacists make daily rounds with the healthcare team for all inpatients, which offers the opportunity to discuss pharmaceutical needs of each patient and identify potential problems.

Our automated Composite Healthcare System (CHCS) identifies patients' allergies and drug regimens in each computer record. This system also allows us to make extensive use of computer drug order entry and barcoding. An important new initiative is the new Pharmacy Data Transaction System (PDTS) that will link our military medical facilities, our Mail Order Pharmacy and the commercial pharmacies our patients use to give us an accurate record of all their prescription medications. This new information system will be an important tool in preventing adverse drug events.

Military medical facilities take special precautions for the storage and use of high hazard drugs such as chemotherapy agents. They also use unit dose systems and pharmacy-based IV preparation to minimize the risk of error.

Within the Military Health System, our pharmacists are vital members of the Healthcare Team. That team collaborates daily on how to improve healthcare and ensure the safety of our patients. This collaboration takes place in the policy-making setting as well as in our hospitals and clinics. We strongly support the Partnership's efforts to reach out to the spectrum of players involved in the care of our patients: providers, healthcare organizations, pharmaceutical industry, and patients themselves.

The Department of Defense continues to seek opportunities to improve the care of our beneficiaries and strongly endorse the best practices identified by the National Safety Partnership as important steps to make medications safer for all our patients.

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Statement of

Beverly L. Malone, PhD, RN, FAAN
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on the launch of the
National Patient Safety Partnership's

Preventable Adverse Drug Events Initiative

May 12, 1999

Today is Florence Nightingale's birthday, the culmination of National Nurses Week. Nightingale is considered the founder of modern nursing. What better day for the American Nurses Association to join with the National Patient Safety Partnership to launch NPSP's Preventable Adverse Drug Events Initiative?

Adverse drug events are a serious public health care problem because of the large number of drugs, doses, and drug treatment regimens currently available and the many changes in the manner in which health care is being provided today. The members of NPSP believe there are significant patient safety improvements that can be made through the prevention of adverse events associated with the prescribing, dispensing and administering of medications. To that end, it advances this initiative aimed at reducing preventable adverse drug events.

America's health care consumers need more concrete and readily available information about what to do in partnership with their nurse or physician to ensure better medication information exchange. The word must get out to as many as possible.

The registered nurses of America, through representation by the American Nurses Association in the National Patient Safety Partnership, share a keen interest in advancing quality, safe practices for those receiving health care. Nurses have first-hand awareness that adverse events related to drug prescription, practices, packaging procedures and systems occur all too often. ANA supports the NPSP's call for improving outcomes by prevention. The identification of best practices or model practices is certainly the way to begin that process.

Nurses are reassured to see the NPSP's "questions patients should always ask about medications" and are encouraged by the outline of current best practices for patients/consumers, providing organizations and practitioners, and purchasers. As the only full-service professional association for the country's 2.6 million nurses, ANA believes quality safe patient outcomes begin with individual responsibility.

The ANA and the NPSP call on health care consumers, patient advocacy groups, the pharmaceutical industry, health care practitioners and health care organizations to make a commitment to adopt certain practices and to work together to implement them, as well as to develop additional ways to reduce adverse drug events.

Here are just two examples of such practices:

--We urge the prominent display of critical patient information, such as drug allergies and medication regimens, on every patient record. Dosage adjustments for children must be highlighted. We must not continue to consider children as little adults and apportion care delivery as such. We must take a similar approach with the frail elderly.

--We must limit accessibility to, and control the use of, highly toxic or other high-hazard drugs such as potassium chloride or concentrated epinephrine.

Taking just these two steps would cost little or nothing to implement. However, ANA and the NPSP recognize that an investment may be required for some, and we call upon health care organizations and the pharmaceutical industry to make the investment in the interest of patient safety.

ANA stands strongly behind the position that the health care and pharmaceutical industries must launch and sustain collaborations directed toward systematic approaches to the prevention of prescription drug errors. Nurses challenge these industries to conduct the needed research as well as to seek collaborations to identify better practices in the future. Defining practices that can predictably effect improvement in terms of increased safety and cost-effectiveness is part of all our jobs.

Integral to such an activity is a non-punitive culture that enhances and supports reporting of adverse or unexpected events to relevant oversight bodies, and that provides feedback about resulting lessons learned and system changes aimed at preventing such events in the future. Our systems and processes are often flawed, and, in the haste to get a quick fix, blame is placed on individuals when an extended look for the source of difficulty is needed.

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Note to Media: To interview registered nurses who can speak on preventable adverse drug events, contact Michael Stewart in the American Nurses Association's Communications Department at (202) 651-7048, or e-mail:RN=RealNews@ana.org. Visit ANA's webpage on patient safety issues at http://www.nursingworld.org/rnnoharm.

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The American Nurses Association is the only full-service professional organization representing the nation's 2.6 million Registered Nurses through its 53 constituent associations. ANA advances the nursing profession by fostering high standards of nursing practice, promoting the economic and general welfare of nurses in the workplace, projecting a positive and realistic view of nursing, and by lobbying the Congress and regulatory agencies on health care issues affecting nurses and the public.

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The National Patient Safety Partnership is a public-private partnership dedicated to improving health care in general and patient safety in particular by reducing adverse events and untoward outcomes of health care or health care-related processes.

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SENTINEL EVENT **ALERT**

Joint Commission
on Accreditation of Healthcare Organizations

A publication of the Joint Commission on Accreditation of Healthcare Organizations

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Issue One
2-27-98

"The way to prevent tragic deaths from accidental intravenous injection of concentrated KCl is excruciatingly simple -- organizations must take it off the floor stock of all units. It is one of the best examples I know of a 'forcing function' -- a procedure that makes a certain type of error impossible."
Lucian L. Leape, M.D.
Harvard School of Public Health

New Publication

We are pleased to introduce the first issue of *Sentinel Event Alert,* a periodic publication dedicated to providing important information relating to the occurrence and management of sentinel events in Joint Commission-accredited health care organizations. *Sentinel Event Alert,* to be published when appropriate as suggested by trend data, will provide ongoing communication regarding the Joint Commission's Sentinel Event Policy and Procedures, and most importantly, information about sentinel event prevention. It is our expectation and belief that in sharing information regarding the occurrence of sentinel events, we can ultimately reduce the frequency of medical errors and other adverse events.

Initially, *Sentinel Event Alert* will be mailed to the organization chief executive officers and Joint Commission survey coordinators, however, it is expected that eventually *Sentinel Event Alert* will be sent via broadcast fax. In the future, staff from the Joint Commission will be contacting your organization to collect appropriate fax and E-mail addresses.

While the topic of this first issue is particularly relevant to acute care facilities, we will share information of relevance to all accredited organizations in future issues.

"Unfortunately, there are too many in health care who feel that if it hasn't happened to them, the adverse experiences of others do not apply. That is why potassium chloride concentrate vials can still be found in patient care areas."
Michael Cohen, MS, FASHP, President, Institute for Safe Medication Practices

Medication Error Prevention -- Potassium Chloride

In the two years since the Joint Commission enacted its Sentinel Event Policy, the Accreditation Committee of the Board of Commissioners has reviewed more than 200 sentinel events. The most common category of sentinel events was medication errors, and of those, the most frequently implicated drug was **potassium chloride (KCl).** The Joint Commission has reviewed 10 incidents of patient death resulting from misadministration of KCl, eight of which were the result of direct infusion of concentrated KCl. In all cases, a contributing factor identified was the availability of concentrated KCl on the nursing unit. In six of the eight cases, the KCl was mistaken for some other medication, primarily due to similarities in packaging and labeling. Most often, KCl was mistaken for sodium chloride, heparin or furosemide (Lasix).

***Issue For Consideration*: In light of this experience, the Joint Commission suggests that health care organizations NOT make concentrated KCl available outside of the pharmacy unless appropriate specific safeguards are in place.**

The Joint Commission makes this information available to assist health care organizations in reducing their risk of sentinel events. Health care organizations should consider the risk described in the Sentinel Event Alert, *and determine their own most appropriate and effective responses to that risk.*